

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
EFFICACY REVIEW - I

Antimicrobial Program Branch

IN 07-25-88

OUT 10-26-88

Reviewed By Emily H. Mitchell ^{WEL 11/2/88} Date 10-26-88

EPA Reg. No. or File Symbol 52252-U

EPA Petition or EUP No. None

Date Division Received 08-09-88

Type Product(s) Hospital Sterilant/Disinfectant

Data Accession No.(s) 407505-01, 407505-02, 407505-03, 407505-04 &
407505-05

Product Mgr. No. PM 31 (Lee)

Product Name(s) RENALIN® COLD STERILANT

Company Name(s) Minntech Corporation

Submission Purpose Resubmission with Additional Data / Information
and Revised Label.

Chemical & Formulation Liquid concentrate to be used diluted

Active Ingredient(s): %

Hydrogen Peroxide	20.0%
Peroxyacetic Acid	4.0%

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
EFFICACY REVIEW - II

Antimicrobial Program Branch

EPA Reg. No. or File Symbol 52252-U
Date Division Received 08-09-88
Data Accession No.(s) 407505-01, 407505-02, 407505-03, 407505-04
& 407505-05
Product Manager No. PM 31 (Lee)
Product Name RENALIN® COLD STERILANT
Company Name Minntech Corporation

202.0 Recommendations

202.1 Efficacy Supported by the Data:

- a. The submitted data/information is acceptable and clarifies the previous data report.

203.0 Labeling

~~No adverse comments.~~

"Delete Water Purification Systems"
Revise "Water Systems" to Read Dialysis
machine Water Inlet".

WEC
11/14/88